

Rec'd PCT/PTT 22 APR 2004

PCT/EP2003/011787



Translation

PATENT COOPERATION TREATY

PCT 10/532319

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 032533woCSgn	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/EP2003/011787	International filing date (day/month/year) 24 October 2003 (24.10.2003)	Priority date (day/month/year) 26 October 2002 (26.10.2002)
International Patent Classification (IPC) or national classification and IPC A61K 51/12		
Applicant INFAI INSTITUT FÜR BIOMEDIZINISCHE..		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. ☒ (sent to the applicant and to the International Bureau) a total of 1 sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:
 - ☒ Box No. I Basis of the report
 - ☐ Box No. II Priority
 - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - ☐ Box No. IV Lack of unity of invention
 - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - ☐ Box No. VI Certain documents cited
 - ☐ Box No. VII Certain defects in the international application
 - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand 26 May 2004 (26.05.2004)	Date of completion of this report 29 October 2004 (29.10.2004)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2003/011787

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):

- ☒ The international application as originally filed/furnished
- ☒ the description:
- pages _____ 1-4 _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- pages _____, as originally filed/furnished
- pages* _____, as amended (together with any statement) under Article 19
- pages* 1, 2 received by this Authority on 18 October 2004 (18.10.2004)
- pages* _____ received by this Authority on _____
- ☒ the drawings:
- pages _____ 1/5-5/5 _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (specify): _____
- ☐ any table(s) related to sequence listing (specify): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (specify): _____
- ☐ any table(s) related to sequence listing (specify): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP 03/11787

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	2	YES
	Claims	1	NO
Inventive step (IS)	Claims		YES
	Claims	1, 2	NO
Industrial applicability (IA)	Claims	1, 2	YES
	Claims		NO

2. Citations and explanations

This report makes reference to the following documents:

D1: SCHADEWALDT P ET AL: "APPLICATION OF ISOTOPE-SELECTIVE NONDISPERSIVE INFRARED SPECTROMETRY (IRIS) FOR EVALUATION OF [¹³C]OCTANOIC ACID GASTRIC-EMPTYING BREATH TESTS: COMPARISON WITH ISOTOPE RATIO-MASS SPECTROMETRY (IRMS)", CLINICAL CHEMISTRY, AMERICAN ASSOCIATION FOR CLINICAL CHEMISTRY, WINSTON, US, vol. 43, no. 3, 1997, pages 518-522, XP1018908, ISSN: 0009-9147

D5: PFAFFENBACH B ET AL: "Nicht-invasiver ¹³C-Oktansäureatemtest zur Messung der Magenentleerung einer festen Testmahlzeit - Korrelation mit der Szintigraphie bei Diabetikern und Reproduzierbarkeit bei gesunden Probanden", Z. GASTROENTEROL., vol. 33, no. 3, MARCH 1995 (1995-03), pages 141-145, XP8013991, ISSN: 0044-2771

1. D5 discloses a process for determining gastric emptying by the oral ingestion of a test substance and measurement of residence time in the stomach,

the test substance containing ^{13}C -octanoic acid bound to egg yolk (page 142, right-hand column, paragraph 6; page 144, left-hand column, paragraph 2). The measured variables are evaluated independently of endogenous conversion factors.

Therefore, all the features of claim 1 are known from D5 and the subject matter of this claim is consequently not novel within the meaning of PCT Article 33(2).

2. Dependent claim 2 does not contain any features which, in combination with the features of claim 1, meet the PCT requirements for inventive step, since the test meal specified in claim 2 is known from D1.